

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

JUDY WETHINGTON, et al.,	:	Case No. C-1-01-441
	:	
Plaintiffs,	:	Judge Spiegel
	:	
vs.	:	
	:	
PURDUE PHARMA, L. P., et al.,	:	
	:	
Defendants.	:	

**PLAINTIFF WETHINGTON’S MOTION TO RECONSIDER ORDER
DENYING CLASS CERTIFICATION**

Plaintiffs request that the Court reconsider and withdraw its denial of Plaintiffs’ motion for class certification. Plaintiffs make this request pursuant to Federal Rule of Civil Procedure 23 (c) (1). Federal Rule 23 (c) (1) provides that Class Certification Orders “may be altered or amended before the decision on the merits”. Plaintiffs make this request because recent developments reveal that class certification is appropriate and because the opinion reveals that the Court reviewed the merits of Plaintiffs’ claims when it denied class certification status.

Additional support is included in the attached memorandum in support of the motion.

Respectfully submitted,

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MEMORANDUM IN SUPPORT

BACKGROUND

On September 30, 2003 this Court issued its Order denying Plaintiffs' motion to certify the litigation as a class action.¹ The Court based its denial on its belief that a common issue did not exist. According to the Court, Plaintiffs "failed to meet the commonality prong of Rule 23 (a) (2)." Order at 27.

The Court's Order failed to consider two important events that demonstrate that common issues exist regarding the design and manufacture of OxyContin and OxyContin's addictive characteristics and the warnings that Defendants provided. After Plaintiffs' submitted their substantive pleadings, Marek Zakrzewski, PhD an assistant Director at Defendant Purdue and a Purdue researcher, disclosed in a complaint against Purdue that the manufacturing process used by Purdue contributed to addiction-related problems experienced by members of the class. Additionally, subsequent to the Court's Order, the United States Drug Enforcement Agency ("DEA") issued a report that found that OxyContin is highly addictive. This finding directly contradicts Defendants' contention that OxyContin is not addictive.

¹ Plaintiffs are attaching a copy of the Order as exhibit "A"?

Zakrzewski Whistle Blower Complaint

According to the Zakrzewski complaint², Dr. Zakrzewski conducted research on Oxycodone HCl, a narcotic used in Oxycontin. Purdue terminated his employment after he informed management that Oxycontin posed serious negative implications for patients.

According to his research and testing, Zakrzewski discovered that the dissolution speed varied in Oxycodone HCl. Purdue used the faster dissolving form of Oxycodone HCl when it manufactured Oxycontin. This form Oxycodone HCL dissolved more quickly into the human body than expected and caused overdosing and to addiction.

The FDA based its approval to market Oxycontin on the belief that only one form of Oxycodone HCl existed. Dr. Zakrzewski's findings raise serious issues regarding the rate that Oxycodone dissolved and the probability of a user becoming addicted.

When Dr. Zakrzewski shared his findings with Purdue's management, Purdue forbade him from conducting further investigations of dissolution of Oxycodone HCl. Dr. Zakrzewski advocated further testing to ensure that the drug, as it was being marketed and sold, was safe for public use. Purdue, nonetheless,

² A copy of Dr. Zakrzewski's complaint is attached as Exhibit "B".

discouraged further testing because Purdue sought to avoid problems with the FDA.

In addition to analyzing the rate that the various forms of Oxycodone HCL dissolve, Dr. Zakrzewski also measured particle size of Oxycodone HCL. Particle size influences the dissolution speeds of the chemical. Dr. Zakrzewski discovered that the method Purdue used to measure particle sizes was inaccurate. When he made this discovery, he developed a new method to measure particle size. He also proposed new and tighter particle size specifications.

According to Dr. Zakrzewski the size of the particles is important because smaller particles dissolve faster than bigger particles. Thus, Purdue when it manufactures Oxycontin must control particle size to control dissolution speed. By failing to control particle size, Purdue produced Oxycontin that dissolved too fast and led to overdose and addiction.

When Dr. Zakrzewski reported his suggestions and conclusions that Purdue adopt a tighter particle size specification, management refused to adopt these specifications and forbade him from communicating with the regulatory department within the company. Management also forbade him from including this information in any written report.

According to Dr. Zakrzewski, Purdue's management ignored FDA guidelines and his findings and adopted the position that the differences in

dissolution rates in the Oxycontin were not significant. Purdue also ignored Dr. Zakrzewski's report that Purdue may be using two different forms of Stearyl Alcohol in the production of Oxycontin. The type of Stearyl Alcohol used may have a material affect on the dissolution of Oxycontin.

DEA Report

In October of 2003, the DEA issued a report entitled OxyContin Diversion & Abuse³. In the report, the DEA states that OxyContin is "highly addictive". DEA report at 3⁴. The DEA also states that the current formulation of OxyContin was flawed and that Purdue and Abbott should reformulate OxyContin to reduce abuse of the product, particularly by injection.⁵ DEA report at 8.

³ A copy of the October 2003 Report is attached as Exhibit "C".

⁴ The October 2003 Report provides the following:

- OxyContin[®] is highly-addictive ~ Abusers can easily compromise the controlled release formulation for a powerful morphine-like high

⁵ The October 2003 Report provides the following:

DEA is working closely with the FDA to strongly urge the rapid reformulation of OxyContin[®] by Purdue Pharma, to the extent that it is technically possible, in order to reduce the abuse of the product, particularly by injection.

ARGUMENT

I. THE COURT SHOULD WITHDRAW ITS ORDER DENYING CLASS CERTIFICATION AND RECONSIDER ITS ORDER

A. The Recently Disclosed Information Creates Common Issues

Throughout the litigation, Purdue and Abbott have asserted that OxyContin is not addictive⁶ and that the package insert clearly identifies the potency of the opioid. *See* Order at 20. Yet, Dr. Zakrzewski's disclosures regarding Purdue's manufacturing process demonstrate that common issues exist regarding the addictive nature and characteristics of OxyContin and the reason members of the class abused OxyContin. Additionally, the DEA's October report expressly states that the DEA has found that OxyContin is highly addictive. Purdue and Abbott, moreover, readily will admit that they failed inform Physicians regarding Dr. Zakrzewski's findings or that OxyContin was highly addictive.

This admitted failure to warn demonstrates that class wide common issues exist concerning whether Purdue and Abbott fulfilled their legal duty to educate the medical community. *See Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 58 Ohio St.3d 147, 149 (1991) (drug manufacturer has a duty to warn and educate doctors of the risks of prescribing medication). These new disclosures, moreover, reveal that the learned intermediary defense is irrelevant because Purdue and Abbott failed to adequately warn the learned intermediaries. Order at 25. Thus, the

⁶ *See* Paul Goldheim Declaration at ¶ 36 (OxyContin is not addictive)

Court should reconsider its important finding that the learned intermediary defense applies.

Indeed, the United States Food and Drug Administration earlier this year concluded that Purdue and Abbott's standard warning failed to warn physicians of the dangers of OxyContin. "Your journal advertisements [*Journal of the American Medical Association*] omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective." The FDA emphasized that "[I]t is **particularly disturbing that your November Ad would tout "Life With Relief," yet fail to warn that patients can die from taking OxyContin.**"⁷ (emphasis added).

These issues regarding Defendants' failure to warn and Defendants' manufacturing process involve only the conduct of Defendants. An examination of the circumstances of individual members of the class is unnecessary. Thus, based on this newly disclosed information, the Court should withdraw its Opinion and reconsider the class certification issue. Of course, Plaintiffs request a reasonable opportunity to conduct discovery on these previously unknown and undisclosed issues.

⁷ January 17, 2003 correspondence between FDA and Purdue, Attached as Exhibit "D".

B. The Court Should Reconsider its Order Because the Court Based its Order on the Merits of the Litigation

The law is clear that the Court may not decide class certification based on the merits of Plaintiffs' claims. *See Eisen v. Carlisle & Jacqueline*, 417 U.S. 156 (1974). This Court's Order, however, reflects that the Court considered the merits when it decided the class certification issue. For example, the Court appears to have found that the benefits of the drug outweighed the risk. Order at 27-28.

The Court also evaluated the merits when it concluded that the Learned Intermediary Doctrine protects Defendants. Based on the limited record, the Court found that Defendants proffered evidence regarding the package insert. Based on this proffer, the Court found "that doctors were adequately warned of the powerful dosage of OxyContin relative to morphine, and thus the Learned Intermediary Doctrine discharges the duty to warn from the manufacturer to the physician." Order at 26.

The Plaintiffs, however, presented contrary evidence. Plaintiffs produced evidence that for the majority of the class period the package insert failed to provide an adequate warning. In July 2001, after Plaintiffs initiated this action, Purdue materially changed the OxyContin® labeling to add a "Black Box Warning". Purdue, after consulting with the FDA, recognized that the literature, including the package inserts and other materials distributed by Purdue and Abbott, failed to educate adequately the medical community of the risks and dangers of

OxyContin®. When the FDA announced that Purdue had decided to change its warnings, the FDA specifically stated that the "new labeling **is intended to change prescription practices** as well as **increase the physicians' focus on the potential for abuse, misuse, and diversion.**" (emphasis added).⁸ This important warning previously was unknown by the physicians and the people who suffered injury and died from OxyContin®. The Court, therefore, prejudged the merits of Plaintiffs' claims when it failed to find that common issues exist regarding whether Purdue and Abbott adequately discharged its duty to warn physicians.

CONCLUSION

For the reasons contained in this Memorandum, the Court should withdraw its Order denying class certification and reconsider its denial of class certification.

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⁸ July 25, 2001 FDA Talk Paper, A copy of the Talk Paper is attached as Exhibit "E".

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CERTIFICATE OF SERVICE

I certify that a copy of Plaintiff Wethington's Motion and Memorandum in Support of Reconsideration was served by regular United States mail, postage prepaid and by Electronic Service on the following counsel for Defendants this 30th day of October 2003:

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